RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-8-24
STANDARDS FOR BIRTHING CENTERS

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1200-8-24-.01 DEFINITIONS.

(1) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(2) Birthing Center. Any institution, facility, place or building devoted exclusively or primarily to the provision of routine delivery services and postpartum care for mothers and their newborn infants.

(3) Board. The Tennessee Board for Licensing Health Care Facilities.

(4) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary functions in a patient, whether by mechanical devices, chest compression, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(5) Certified Nurse Midwife (CNM). A registered nurse currently licensed as such by the Tennessee Board of Nursing and certified by the American College of Nurse-Midwives and qualified to deliver midwifery services.

(6) Certified Professional Midwife (CPM). A North American Registry of Midwives (NARM) certified midwife, who must have midwifery skills and experience evaluated and pass written and skills examinations.

(7) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(8) Competent. A patient who has decision-making capability.

(9) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(Rule 1200-8-24-.01, continued)

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(10) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(11) Department. The Tennessee Department of Health.

(12) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(13) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(14) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(15) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed legal guardian or conservator with health care decision-making authority, or the patient's surrogate as determined pursuant to Rule 1200-8-24-.12 or T.C.A. §33-3-220.

(16) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity. injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(17) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(18) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(19) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(20) Legal Guardian. Any person authorized to act for the patient pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(21) Licensee. The person or body to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(22) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(23) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations, and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(24) Medically Futile Treatment. "Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(25) Member of the professional medical community. A professional employed by the birthing center and on the premises at the time of a voluntary delivery.

(26) NFPA. The National Fire Protection Association.

(27) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(28) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed to practice osteopathy by the Tennessee Board of Osteopathic Examiners.

(29) Routine Delivery Services. Services provided by a physician or a certified professional midwife practicing when these rules become final or a certified nurse midwife related to the normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health, promoting a family-centered approach to care and viewing pregnancy and delivery as a normal physiological process requiring limited technological and pharmacological support.

(30) Shall or Must. Compliance is mandatory.

(31) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified medical personnel when a physician is not readily available.

(Rule 1200-8-24-.01, continued)

(32) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(33) Transfer. The movement of a patient to a hospital at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(34) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(35) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

(36) "Voluntary delivery" means the action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a birthing center with any birthing center employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-24-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any birthing center without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Each applicant for a license shall pay an annual license fee of $800.00. The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the birthing center until a license has been issued. Applicants shall not hold themselves out to the public as being a birthing center until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations.

(d) The applicant must prove the ability to meet the financial needs of the facility.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(Rule 1200-8-24-.02, continued)

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a birthing center has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the facilities operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the birthing center is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to, the following:

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate facility owner with one or more corporations; or,

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

5. Corporate stock transfers or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However. if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(Rule 1200-8-24-.02, continued)

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) To be eligible for a license or renewal of a license, each birthing center shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, and 68-11-216.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed November 19, 2003; effective February 2, 2004.*

1200-8-24-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission, of any illegal act in the birthing center;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the facility; and

(e) Failure to renew license.

(2) The board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patient in the facility;

(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,

(d) Any prior violations by the facility of statutes, regulations or orders of the board.

(3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke a birthing center's license.

(4) When a birthing center is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(Rule 1200-8-24-.03, continued)

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the birthing center's license to possible disciplinary action.

(6) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, *T.C.A. §§ 4-5-101, et seq.*

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-208, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-8-24-.04 ADMINISTRATION.

(1) Birthing centers must have a governing body which is legally responsible for:

(a) The overall operation and maintenance of the facility;

(b) The provision of personnel, facilities, equipment, supplies, and services to mothers and families;

(c) Adopting administrative policies regarding patient care;

(d) Appointing an administrator or director responsible for implementing the adopted policies;

(e) Establishing and maintaining a written organizational plan;

(f) Appointing a clinical staff and assuring its competence; and

(g) Documenting all of the above.

(2) When licensure is applicable for a particular job, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.

(3) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A birthing center which violates a required policy also violates the rule and regulation establishing the requirement.

(4) Policies and procedures shall be consistent with professionally recognized standards of practice.

(5) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV virus in the event that an employee of the facility, a student studying at the facility; or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(6) The facility and its employees shall adopt and utilize standard precautions of the Centers for Disease Control (CDC) for preventing transmission of infections, HIV, and communicable diseases.

(Rule 1200-8-24-.04, continued)

(7) All birthing centers shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.

(8) Each birthing center utilizing students shall establish policies and procedures for their supervision.

(9) Each birthing center shall establish policies for permitting visitors.

(10) No birthing center shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the department, the Adult Protective Services, or the Comptroller of the State Treasury. A birthing center shall neither retaliate nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-222.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-8-24-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Prior to admission for services, the birthing center shall inform the patient of:

(a) The qualifications of the birthing center staff;

(b) The risks related to out-of-hospital childbirth;

(c) The benefits of out-of-hospital childbirth; and

(d) The possibility of referral or transfer if complications arise during pregnancy or labor.

(2) The birthing center clinical staff shall obtain the patient's written consent for birthing center services.

(3) The signed consent form shall be included with the patient's individual clinical record.

(4) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(5) Birthing center patients are limited to those women who are initially determined to be at low risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk.

(6) Each birthing center shall establish a written risk assessment system which shall be a part of the policy and procedure manual. The individual risk assessment shall be included in the patient's clinical record.

(7) Written policies, procedures and practice guidelines for management of emergencies and discharge must be developed and implemented.

(8) Each birthing center shall have a written agreement with a hospital(s), which is licensed to provide obstetrical services, for emergency care. Each physician practicing or consulting in the birthing center shall have admitting privileges at a designated back-up hospital.

(9) The birthing center shall have written practice guidelines which shall include at a minimum:

(Rule 1200-8-24-.05, continued)

(a) The name, address, telephone numbers and contact persons of the licensed transport service, the hospital licensed to provide emergency obstetrical and neonatal services and other hospitals in the vicinity;

(b) The criteria to determine risk status which require medical consultation or transfer to a hospital will be outlined in the clinical practice guidelines; and,

(c) The criteria and practice guidelines for transfer shall be readily accessible to clinical staff at all times.

(10) The names and telephone numbers of the ambulance service, neonatal transport service, and hospital shall be clearly posted at each telephone in the birthing center.

(11) Infant Abandonment.

(a) Any birthing center shall receive possession of any newborn infant left on birthing center premises with any birthing center employee or member of the professional medical community, if the infant:

1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;

2. Is left in an unharmed condition; and

3. Is voluntarily left by a person who purported to be the child's mother and who did not express an intention of returning for the infant.

(b) The birthing center, any birthing center employee and any member of the professional medical community at such birthing center shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The birthing center shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The birthing center may provide the parent contact information regarding relevant social service agencies, shall provide the mother the name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinguishment of the infant. If practicable, the birthing center shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.

(c) The birthing center, any birthing center employee and any member of the professional medical community at such birthing center shall perform any act necessary to protect the physical health or safety of the child.

(d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the birthing center shall contact the Department of Children's Services, but shall not do so before the mother leaves the birthing center premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.

(e) Notwithstanding any provision of law to the contrary, any birthing center, any birthing center employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that

(Rule 1200-8-24-.05, continued)

nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause of action based upon violation of such existing standard of care for medical treatment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-255.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002.*

1200-8-24-.06 BASIC BIRTHING CENTER FUNCTIONS.

(1) Quality Assurance. The birthing center governing body must ensure that there is an established program for evaluating the quality of direct care services to childbearing families, and the environment in which the services are provided. with an organizational plan to identify and resolve problems.

(2) Staff.

(a) The governing body must ensure that there are adequate numbers of qualified and, where required, licensed personnel to provide services needed by mothers and families and to provide for safe maintenance of the birthing center.

(b) The governing body must appoint a medical director who:

1. Is a qualified specialist in obstetrics/gynecology or family practice;

2. Approves all policies, procedures and practice guidelines for the medical management of care;

3. Approves standardized criteria for admission screening and monitoring the risk status of each mother during pregnancy, labor, birth and postpartum; and

4. Is available for consultation and referral in obstetrics or pediatrics or has made arrangements with a qualified physician for these services.

(3) Equipment.

(a) A readily accessible emergency cart or tray for the mother, equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.

(b) A readily accessible emergency cart or tray for the newborn, equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.

(c) Properly maintained equipment for routine care of women and neonates including but not limited to:

1. A heat source for infant examination or resuscitation;

2. Transfer incubator or isolette or demonstrated capability of ready access to transfer incubator;

3. Sterilizer or demonstration of sterilizing capability;

4. Blood pressure equipment, thermometers, fetoscope/doptone;

5. Intravenous equipment;

6. Oxygen equipment for mother and newborn; and,

7. Instruments for episiotomy and repair.

(4) Prenatal Care. The physician, certified professional midwife and nurse-midwife shall ensure that patients have adequate education and prenatal care by generally accepted definitions. Records of this care should be available in the center at the time of admission. When, in the course of prenatal care. risk factors are identified which preclude childbirth at the center, the woman shall be referred for care in a hospital setting and her prenatal records made available to the attending clinicians.

(5) Surgical Services. Surgical procedures shall be limited to those normally accomplished during uncomplicated childbirth, such as episiotomy and repair, and must not include operative obstetrics or cesarean section.

(6) If intervention beyond what is allowed in the practice guidelines is required at any time during the course of pregnancy and/or labor, the woman and her newborn must be managed at a more intensive level of care.

(7) Laboratory Services. The birthing center shall have the capacity to perform on site routinely necessary tests such as hematocrit and urinalysis for glucose, protein, bacteria, and specific gravity.

(8) Intrapartum Care. Labor shall not be inhibited, stimulated. or augmented with chemical agents during the first or second stage of labor. Drugs for induction or augmentation of labor, vacuum extractors, forceps, continuous electronic fetal monitoring and ultrasound imaging are not appropriate during normal labor. A nurse midwife. certified professional midwife or physician must be in attendance or available to attend during all stages of the delivery.

(9) Analgesia and Anesthesia. General and conduction anesthesia shall not be administered at birthing centers. Local anesthesia for pudendal block may be performed. Systemic analgesia may be administered, but pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

(10) Postpartum Care. Mothers and infants must be discharged in accordance with standards set by the clinical staff and specified in the policy and procedures manual, including laboratory tests required by state laws. A program for prompt follow-up care and postpartum evaluation after discharge shall be ensured and outlined in the manual of policies and procedures. This program should include assessment of infant health including physical examination, laboratory screening tests at the appropriate times, maternal postpartum status, instruction in child care including immunization, referral to sources of pediatric care, provision of family planning services, and assessment of mother-child relationship including breast feeding.

(11) Food Services. The birthing center must provide mothers and families with nutritious liquids and snacks as required. Food may be prepared by the family, catered, or prepared in the birthing center's kitchen. Meals that are prepared and served by the birthing center will be subject to local regulations for food preparation and service.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-8-24-.07 BUILDING STANDARDS.

(1) Existing licensed facilities which meet Ambulatory Surgical Treatment Center Codes and Regulations shall be deemed to comply with these standards.

(2) The birthing center must be constructed, arranged, and maintained to ensure the safety of the patient.

(3) The condition of the physical plant and the overall birthing center's environment must be developed and maintained in such a manner that the safety and well being of patients are assured.

(4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the 1999 edition of the Standard Building Code (excluding Chapter I, Administration and Chapter 11, Handicapped Accessibility), the handicap code as required by T.C.A. §68-18-204(a), the most recent edition of the ASHRAE Handbook of Fundamentals, and the 2000 edition of the National Fire Protection Code (NFPA), NFPA 1 including Annex A, the 1999 National Electrical Code and the 2001 Edition of the Guidelines for design and Construction of Hospitals and Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

(5) All new construction and renovations to birthing centers, other than minor alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in birthing centers, including the submission of phased construction plans and the final work drawings and the specifications to each. Phased construction plans, final work drawings, and specifications shall also be submitted prior to any change in facility type.

(6) No new birthing centers shall hereafter be constructed, nor shall major alterations be made to existing facilities, or change in facility type be made without prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new birthing center is licensed or before any alteration or expansion of a licensed birthing center can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.

(7) In the event that submitted materials do not appear to satisfactorily comply with 1200-8-24-.07(4) the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(8) Notice of satisfactory review from the department constitutes compliance with this requirement if construction begins within one hundred eighty (180) days after the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

(9) Existing facilities shall comply with Chapter 19 of NFPA 101 and all of these regulations except as specified otherwise in paragraph (4) above.

(10) The codes in effect at the time of submittal of preliminary plans and specifications, as defined by these regulations, shall be the codes to be used throughout the project.

(Rule 1200-8-24-.07, continued)

(11) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. These plans shall be prepared by an architect or engineer licensed to practice in the State of Tennessee. The plans shall contain a certificate signed by the architect or engineer that to the best of his or her knowledge or belief the plans conform to all applicable codes.

(a) Phased construction plans shall be forwarded to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.

(b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.

(12) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies should be bound in an 8 1/2 x 11 inch folder.

(13) Final review of plans and specifications shall be acknowledged in writing with copies sent to the architect and the owner, manager or other executive of the facility.

(14) All construction shall be executed in accordance with the approved plans and specifications.

(15) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical and Electrical.

(16) Architectural drawings shall include:

(a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;

(b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

(c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units (with color coded fire and smoke walls);

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

(i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel must be indicated for elevators, and,

(j) Code analysis.

(17) Structural drawings shall include:

(a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members; and

(b) Schedules of beams, girders and columns.

(18) Mechanical drawings shall include:

(a) Specifications which show the complete heating, ventilating and, if required, air conditioning systems;

(b) Water supply, sewage and HVAC piping systems;

(c) Pressure relationships which shall be shown on all floor plans;

(d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;

(e) Water supply, sewage and drainage with all lines, risers, catchbasins, manholes and cleanouts clearly indicated as to location, size, capacities, etc., and location and dimensions of septic tank and disposal field; and,

(f) Color coding to show clearly supply, return and exhaust systems.

(19) Electrical drawings shall include:

(a) A certification that all electrical work and equipment are in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;

(b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building; and,

(c) Color coding to show all items on emergency power.

(20) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes. One (1) set of final plans shall be submitted to the department, after final approval is given but prior to occupancy, in such a form as approved by the department.

(21) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.

(a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.

(b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation

(Rule 1200-8-24-.07, continued)

approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.

(22) Laundry Service.

(a) Laundry may be done on- or off-site. If on-site, an area for laundry equipment with counter and storage space shelving shall be provided. Depending on size and occupancy of the center, ordinary household laundry equipment may be provided. (Soiled laundry shall be held in the soiled holding area until deposited in the washer.)

(b) A separate area for storing clean and sterile supplies shall be provided.

(23) Construction and renovation projects shall provide for the safety and protection of patients and personnel.

(24) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.

(a) Any condition on the birthing center site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

(b) Cats, dogs or other animals shall not be allowed in any part of the facility except for specially trained animals for the handicapped. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed February 18, 2003; effective May 4, 2003.*

1200-8-24-.08 LIFE SAFETY.

(1) Any birthing center which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(2) The birthing center shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. Fire drills shall be held at least quarterly for all birthing center personnel in each separate building. There shall be a written report documenting the evaluation of each drill and the executive action recommended or taken for any deficiencies found.

(3) All fires which result in a response by the local fire department shall be reported to the department within five (5) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the birthing center may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the birthing center shall provide such information.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-8-24-.09 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each birthing center must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste, including a specific policy and procedure on containment and repackaging of spilled waste. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation, Precautions in Hospitals";

(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures;

(c) Waste human blood and blood products such as serum, plasma, and other blood components;

(d) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;

(e) All discarded sharps (e.g., hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;

(f) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals; and,

(g) Other waste determined to be infectious by the facility in its written policy.

(3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.

(4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how it will be handled and transported, and how the waste will be treated and disposed of.

(a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(d) Opaque packaging must be used for pathological waste.

(Rule 1200-8-24-.09, continued)

(5) After packaging, waste must be handled and transported by methods ensuring containment and preservation of the integrity of the packaging, including the use of secondary containment where necessary.

(a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal.

(b) Plastic bags of infectious waste must be transported by hand.

(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons.

(a) Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(b) Pathological waste must be promptly treated, disposed of, or placed in refrigerated storage.

(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:

(a) Isolate the area from the public and all except essential personnel;

(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of paragraph (6) of this section;

(c) Sanitize all contaminated equipment and surfaces appropriately; and,

(d) Complete an incident report and maintain a copy on file.

(8) Except as provided otherwise in this rule a facility must treat or dispose of infectious waste by one or more of the methods specified in this paragraph.

(a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure that conditions were met for proper sterilization or disinfection of materials included in the cycle, and appropriate records kept. Proper operation of such devices must be verified at least monthly, and records of the monthly verifications shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) A facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to *T.C.A. §§ 69-*

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3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this rule. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material, and shall be kept on elevated platforms.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-8-24-.10 RECORDS AND REPORTS.

(1) A report of all births, deaths and stillbirths which have occurred in the birthing center shall be filed with the local registrar in the county where the institution is located. The report shall be filed on the third (3rd) working day of each month on a form furnished by the State Registrar. The report shall state whether or not the list is complete for all events which have occurred in the facility during the preceding calendar month, and if not complete, shall show the number of events not included in the report. If no birth, death, or stillbirth occurred in the facility, the words "No Report" shall be entered on the form and forwarded to the local registrar.

(2) The Joint Annual Report, a calendar year statistical report, shall be filed with the department's Bureau of Information Resources no later than sixty (60) days following the twelve (12) months ending December 31.

(3) The birthing center shall report each case of communicable disease to the local county health officer in the mariner provided by existing regulations of the department. Repeated failure to report communicable diseases shall be cause for revocation of a facility license.

(4) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a

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patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

   (i) procedure related injury requiring repair or removal of an organ;

   (ii) hemorrhage;

   (iii) displacement, migration or breakage of an implant, device, graft or drain;

   (iv) post operative wound infection following clean or clean/contaminated case;

   (v) any unexpected operation or reoperation related to the primary procedure;

   (vi) hysterectomy in a pregnant woman;

   (vii) ruptured uterus;

   (viii) circumcision;

   (ix) incorrect procedure or incorrect treatment that is invasive;

   (x) wrong patient/wrong site surgical procedure;

   (xi) unintentionally retained foreign body;

   (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

   (xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the

facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(5) The birthing center shall report information contained in the medical records of patients who have cancer or precancerous or tumorous diseases as provided by existing regulations. These reports shall

(Rule 1200-8-24-.10, continued)

be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(6) The birthing center shall retain legible copies of the records and reports specified in this paragraph for the thirty-six (36) month period following their issuance. Copies of these reports shall be maintained in a single file at a location convenient to the public and, during normal business hours, they shall be promptly produced for the inspection of any person who requests to view them. Each patient and each person assuming any financial responsibility for a patient must be fully informed, before or at the time of admission, of the availability of these reports to the public, of their location within the facility, and given an opportunity to inspect the file before entering into any monetary agreement with the facility.

(a) Local fire safety inspections.

(b) Local building code inspections, if any.

(c) Fire marshal reports.

(d) Department licensure and fire safety inspections and surveys.

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any.

(f) Federal Health Care Financing Administration surveys and inspections, if any.

(g) Orders of the Commissioner or Board, if any.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-8-24-.11 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department and the Tennessee Department of Human Services, Adult Protective Services;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record; and,

(e) To have his or her records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The birthing center must have policies to govern access and duplication of the patient's record.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-8-24-.12 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING FOR INCOMPETENT PATIENTS.

(1) Pursuant to this Rule, each birthing center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks decision-making capacity, including but not limited to allowing the withholding of CPR measures from individual patients. The policies and procedures for determining when resuscitative services may be withheld must respect the patient's rights of self-determination. The birthing center must inform the patient and/or the patient's health care decision-maker of these policies and procedures upon admission or at such time as may be appropriate.

(2) The birthing center should identify, after consultation with the family or responsible party, the name of the health care decision-maker for a patient who is incompetent or who lacks decision-making capacity, who will be responsible, along with the treating physician, for making health care decisions, including but not limited to deciding on the issuance of a DNR order.

(3) Health care decisions made by a health care decision-maker must be made in accord with the patient's individual health care instructions, if any, and other wishes to the extent known to the health care decision-maker. If the patient's specific wishes are not known, decisions are to be made in accord with the health care decision-maker's determination of the patient's desires or best interests in light of the personal values and beliefs of the patient to the extent they are known.

(4) In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf.

(a) The patient's surrogate shall be an adult who:

1. has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available; and

2. consideration shall if possible be given in order of descending preference for service as a surrogate to:

(i) the patient's spouse,

(ii) the patient's adult child,

(iii) the patient's parent,

(iv) the patient's adult sibling,

(v) any other adult relative of the patient, or

(vi) any other adult who satisfies the requirement under part 1 above.

(b) If none of the individuals eligible to act as a surrogate under subparagraph (a), is reasonably available, the patient's treating physician may make health care decisions for the patient after the treating physician either (i) consults with and obtains the recommendations of an institutional ethics committee, or (ii) consults with a second physician who (A) is not directly involved in the patient's health care; (B) either (i) does not serve in a capacity of decision-making or influence or responsibility over the treating physician, or (ii) for whom the treating physician does not exert decision-making, influence or responsibility; and (C) concurs with the treating physician's decision. For the purposes of this rule, "institutional ethics committee"

(Rule 1200-8-24-.12, continued)

means a committee of a licensed health care institution which renders advice concerning ethical issues involving health care.

(5) All patients shall be presumed as having consented to CPR unless there is documentation in the medical record that the patient has specified that a DNR order be written. DNR orders may be written to exclude any portion of the CPR measures deemed to be unacceptable.

(6) In the case of an incompetent patient who has appointed an attorney in fact to act on his or her behalf pursuant to an advance directive or who has a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must reflect that the attorney in fact, guardian or conservator has specified that a DNR order be written. In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf, and reflect that the patient's surrogate and the patient's treating physician have mutually specified that a DNR order be written.

(7) CPR may be withheld from the patient if in the judgment of the treating physician an attempt to resuscitate would be medically futile. Withholding and withdrawal of resuscitative services shall be regarded as identical for the purposes of these regulations.

(8) Procedures for periodic review of DNR orders must be established and maintained. The birthing center must have procedures for allowing revocation or amending DNR orders by the patient, the patient's health care decision-maker, or treating physician. Such change shall be documented in the medical record.

(9) Any treating physician who refuses to enter a DNR order in accordance with provisions set forth above, or to comply with a DNR order, shall promptly advise the patient or the patient's health care decision-maker of this decision. The treating physician shall then:

(a) Make a good faith attempt to transfer the patient to another physician who will honor the DNR order; and,

(b) Permit the patient to obtain another physician.

(10) Each birthing center shall establish, and set forth in writing, a mediation process to deal with any dispute regarding health care decisions, including DNR orders, or the determination of the health care decision-maker.

(11) This rule does not alter any requirements imposed by state or federal law, where applicable, including Title 33, the mental health and developmental disabilities law.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-24-.13 DISASTER PREPAREDNESS.

(1) Physical Facility and Community Emergency Plans.

(a) Every birthing center shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills.

(Rule 1200-8-24-.13, continued)

(b) The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients to other healthcare facilities must have written agreements for emergency transfers. Their agreements may be mutual, i.e., providing for transfer either way.

(c) Copies of the plan(s), either complete or outlines, shall be available to all staff. Provisions that have security implications may be omitted from the outline versions. Familiarization information shall be included in employee orientation sessions and more detailed instructions must be included in continuing education programs. Records of orientation and education programs must be maintained for at least three (3) years.

(d) Drills of the fire safety plan shall be conducted at least once a year on each major work shift, for a minimum of three times a year for each facility. A combined drill of the other internal emergency plans shall be conducted at least once a year. The risk focus may vary by drill. Both types of drills are for the purposes of educating staff, resource determination, testing personal safety provisions and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

(e) As soon as possible, real situations that result in a response by local authorities must be documented. This includes a critique of the activation of the plan. Actual documented situations that provided educational and training value may be substituted for a drill.

(2) Emergency Planning with Local Government Authorities.

(a) All birthing centers shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The facility shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

(b) A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*